UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/663,272	11/25/96	HARRISON L	10308

HM31/0218

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EXAMINER	
VANDERVEGT, F	
ART UNIT	PAPER NUMBER
1644	9

DATE MAILED: 02/18/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.	Applicant(s)
08/663,272	Harrison et al
Examiner	**Group Art Unit**
F. Pierre VanderVegt	1816

☒ Responsive to communication(s) filed on *Sep 8, 1997*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-36* is/~~are~~ pending in the application.

Of the above, claim(s) *8-29* is/~~are~~ withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-7 and 30-36* is/~~are~~ rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☒ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a 371 of PCT/AU96/00085.

Claims 1-36 are currently pending in this application.

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-29 and 36 in Paper No. 7 ½ is acknowledged. The traversal is on the ground(s) that the claimed method of use of the peptides for treatment should not have been separated from the compound claims because they share a special technical feature with the compound under PCT Rule 13.2. This is not found persuasive because Applicant is reminded that the method of treatment is a materially and practicably different method from the method of assay which was the first appearing method of use of the peptides in the application and accordingly was the method of use grouped with the compound claims as per PCT practice. Accordingly, the requirement is still deemed proper. However, upon further consideration, and after speaking with Applicant's representative on February 6, 1998, the Examiner, as a courtesy to Applicant, has elected to modify the Lack of Unity requirement so that the compound claims 1-7, method of treatment claims 30-35 and pharmaceutical composition claim 36 are grouped together as the elected claims, with method of assay claims 8-29 being withdrawn as being drawn to a non-elected invention. Claims 19-29 are drawn to a "Use" of the peptides which appears to read upon the method of assay and are therefore withdrawn along with the assay claims.

Reiterating;

claims 8-29 are withdrawn by Examiner as being drawn to a non-elected invention and claims 1-7 and 30-36, drawn to GAD65 and proinsulin peptides, method of treatment and a pharmaceutical composition, are elected by Applicant and are the subject of examination in this Office Action.

Claim Objections

2. Claims 5-7 and 34-36 are objected to under 37 CFR 1.182(d) for failing to disclose the Sequence I.D. NOS. of the amino acid sequences.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the Applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the Applicant for patent.

4. Claims 1-5 and 7 are rejected under 35 U.S.C. 102(a & e) as being anticipated by U.S. Patent No. 5,473,049 to Obermeier et al (A on form PTO-892).

The '049 patent teaches recombinant proinsulin peptides which comprise the sequence (claimed as "X_2" in the instant application) "FFYTPKTRREAED" and further comprising flanking sequences which comprise 0 to 40 amino acids residues (SEQ ID NOS: 4-7 in particular). Applicant is reminded that the term "comprising" recited in claims 1 and 7 is open-ended. It would open up the sequences to include other residues up to and including intact proteins comprising said sequences. Applicant is further reminded that a composition is a composition irrespective of what its intended use is (see *In re Tuominen*, 213 USPQ 89 (CCPA 1982)). The claimed recitation of intended use as a modifier of T cell function does not carry patentable weight per se. The claimed terms merely set forth a property inherent in an otherwise old proinsulin composition. The prior art teaching anticipates the claimed invention.

5. Claims 1-4, 6-7, 30-33 and 35-36 are rejected under 35 U.S.C. 102(a & e) as being anticipated by WO 92/20811, Zymogenetics et al (1C on form PTO-1449).

The '811 PCT document teaches recombinant GAD peptides which comprise the sequence (claimed as "X_2" in the instant application) "FWYIPPSLRTLED" and further comprising flanking sequences which comprise 0 to 40 amino acids residues (Fig. 2a-2e in particular). Applicant is reminded that the term "comprising" recited in claims 1 and 7 is open-ended. It would open up the sequences to include other residues up to and including intact proteins comprising said sequences. Applicant is further reminded that a composition is a composition irrespective of what its intended use is (see *In re Tuominen*, 213 USPQ 89 (CCPA 1982)). The claimed recitation of intended use as a modifier of T cell function does not carry patentable weight per se. The claimed terms merely set forth a property inherent in an otherwise old GAD composition. The '811 PCT document further teaches that the GAD peptides can be used as a pharmaceutical composition in a method of treatment to induce immunological tolerance or anergy in an individual predisposed or already mounting an immune response to GAD as an autoantigen (pages 20, line 29 to page 21, line 29 in particular). It is noteworthy that the process of inducing immunological tolerance includes within its scope the modification of responses to an antigen within both the T cell and B cell compartments. The prior art teaching anticipates the claimed invention.

6. Claims 1-4, 6-7, 30-33 and 35-36 are rejected under 35 U.S.C. 102(a & e) as being anticipated by U.S. Patent No. 5,674,978 to Tobin et al (B).

The '978 patent teaches recombinant GAD protein which comprises the sequence (claimed as "X_2" in the instant application) "FWYIPPSLRTLED" and further comprising flanking sequences which comprise 0 to 40 amino acids residues (Fig. 3a-3d in particular). Applicant is reminded that the term "comprising" recited in claims 1 and 7 is open-ended. It would open up the sequences to include other residues up to and including intact proteins comprising said sequences. Applicant is further reminded that a composition is a composition irrespective of what its intended use is (see *In re Tuominen*, 213 USPQ 89 (CCPA 1982)). The claimed recitation of

intended use as a modifier of T cell function does not carry patentable weight per se. The claimed terms merely set forth a property inherent in an otherwise old GAD composition. The '978 patent further teaches the use of GAD protein as a pharmaceutical composition in a method of treatment to inactivate GAD reactive T cells and that this inactivation prevents long-term development of insulitis and diabetes in treated subjects (column 28, line 29 through column 29 in particular). The prior art teaching anticipates the claimed invention.

7. Claims 1-4, 6-7, 30-33 and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaufman et al (U).

Kaufman et al teaches the use of an effective amount of human GAD peptide (Fig 1 in particular) to tolerize GAD reactive T cells, a modification of their function, in a subject (NOD mouse) and thereby block the development of T cell autoimmunity to other beta cell antigens and, subsequently, prevent the onset of insulitis and diabetes (Abstract in particular). Kaufman et al also teaches that this data would be applicable in immunotherapies for human IDDM patients (page 72 in particular). The method of Kaufman et al uses the full length human GAD peptide and, therefore, inherently comprises the amino acid segments and sequences particularly stated in the instant claims. The prior art teaching anticipates the claimed invention.

Conclusion

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

9. Effective February 7, 1998, the Group and Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1644.

10. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center

located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014. *Communications which are not to be entered into the record, such as proposed amendments, should be clearly marked "DRAFT" and faxed to (703)305-7939.*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Monday through Friday from 8:00 am to 4:30 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

February 16, 1998
F. Pierre VanderVegt, Ph.D.
Patent Examiner
Art Unit 1644

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644